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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,878	10/12/2005	Terrence R Langford	122123.00004US2	4470

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EXAMINER	
DELCOTTO, GREGORY R	

ART UNIT	PAPER NUMBER
1751	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/552,878	LANGFORD, TERRENCE R	
	Examiner	Art Unit	
	Gregory R. Del Cotto	1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 14-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/06, 10/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a method for ensuring sterility in a cleaning system for an instrument.

Group II, claim(s) 14-22, drawn to an apparatus for cleaning and sterilizing an instrument.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claims 1-13, drawn to a method for ensuring sterility in a cleaning system for an instrument, and claims 14-22, drawn to an apparatus for cleaning and sterilizing an instrument, lack the same or corresponding special technical features, so there is no unity of invention between claims 1-13 and claims 14-22.

During a telephone conversation with Gavin Milczarek-Desai on October 25, 2006, a provisional election was made with traverse to prosecute the invention of Group II, claims 14-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

Note that, with respect to EP 356,896, EP 470,116, and EP 664,715, these references have not been considered, as indicated in the attached listing of the references, because no statement of relevancy has been provided with these non-English documents. The submission of these references fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 17, and 19-22 rejected under 35 U.S.C. 102(b) as being anticipated by Kasting, Jr. et al (5,520,893) or Holsclaw et al (US 6,482,370).

Kasting, Jr. et al teach medical instruments, including stainless steel, plastic tubing, and the like, are sterilized in a portable apparatus that provides a low volume,

high pressure flow of continuously circulating water containing from about 2 to 6 ppm of ozone. The apparatus for sterilizing articles comprises an open chamber for containing articles to be sterilized, said chamber receiving a recirculated supply of water containing ozone for immersion contact with the articles to be sterilized; an openable lid associated with said open chamber for substantially precluding ozone that escapes from the water from escaping from said chamber when said apparatus is being operated, said lid comprising an ozone destroying substance; means for recirculating a flow of the water containing ozone through said cahmber sufficient for immersion contact of said articles in the ozone containing water, said recirculating means including: an ozone generator of gernrating ozone, a high voltage transformer for supplying power to said generator, said transformer being a step up transformer and having an output voltage of from at least about 8000 to 12000 volts, means for injecting ozone generated by said generator into water in a concentration of at least about 0.2 ppm, a pump having a fluid intake and a fluid discharge for recirculating water containing ozone at a pressure of from about 25 to 40 psig and at a rate of from about 1 to 4 gallons per minute, a first fluid flow conduit nterconnecting said chamber and said intake side of said pump for flow from said chamber to said pump; a second fluid flow conduit interconnecting said ozone injecting means with said dischare side of said pump; and a third fluid floe conduit interconnecting said ozone injecting means with said chamber for recirculating flow of the water containing ozone through said chamber, and safety means electrically connected to said lid for precluding the operation of said recirculating means when said lid is open. See claim 1. Kasting, Jr. et al disclose the claimed invention with sufficient

specificity to constitute anticipation.

Accordingly, the teachings of Holsclaw et al anticipate the material limitations of the instant claims.

Holsclaw et al teach an apparatus for generating ozone and injecting ozone into water and circulating the ozone containing water through dental water lines in a cleaning mode, and providing a source of disinfected/sterilized water for dental applications in an operation mode, comprising a reservoir for containing water; an ozone generator for producing ozone, a means for injecting ozone into said water forming ozonated water, means for pressurizing said reservoir, means for depressurizing said reservoir, a pump for recirculating said water from said reservoir through said means for injecting ozone, a power supply for said ozone generator and said pump, at least one line for circulating said ozonated water to at least one dental offeratory wherein a portion of said ozonated water is used in a dental application and a portion is recirculating to said reservoir, and means for controlling the activation of said ozone generator and said pump for selected operating intervals at selected periods of cycle times. See claim 1. The method provides ozonated water to dental handpieces and other dental implements. See column 3, lines 30-40. Holsclaw et al dislclose the claimed invention with sufficient specificity to constitute anticipation.

Accordingly, the teachings of Holsclaw et al anticipate the material limitations of the instant claims.

Claims 14-22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO02/32467.

467 teaches an apparatus for cleaning medical equipment comprising a supply of filtered water, a supply of ozonated water containing a predetermined concentration of water and means for delivering first a flow of filtered water over the surfaces of the equipment to be cleaned for a predetermined time followed by a flow of ozonated water over said surfaces for a predetermined time to disinfect the surfaces. See Abstract. The ozonated water is de-ionized prior to ozonating to the predetermined concentration. In the system, unozonated water was pumped through the system for 10 minutes and then ozonated water was pumped through the system for 6 minutes which achieves a high level disinfection. See page 6, lines 1-15. After the cycle, rinse water and ozonated water may also be flowed over the outer surface of the endoscopes to disinfect these as well. See page 7, lines 10-35. The apparatus is comprises a means for filtering the tap water used in the process to provide a supply of filtered water. See claims 7-12. '467 discloses the claimed invention with sufficient specificity to constitute anticipation.

Accordingly, the teachings of '467 anticipate the material limitations of the instant claims.

Claims 15, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasting, Jr. et al (US 5,520,893) or Holsclaw et al (US 6,482,370) as applied to claims 14, 17, and 19-22 above, and further in view of WO02/32467.

Kasting, Jr. et al or Holsclaw et al are relied upon as set forth above. However, neither reference teaches the use of a filtering means in addition to the other requisite elements of the apparatus as recited by the instant claims.

'467 is relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a filtering means in the apparatus taught by Kasting, Jr. et al or Holsclaw et al, with a reasonable expectation of success, because '467 teaches the use of a filtering means in a similar apparatus for disinfecting medical instruments to provide filtered water which contacts said medical instruments and further, it would be desirable to one skilled in the art to use such a filtering means as a method of further cleaning, disinfecting, and purifying the water which comes into contact with medical instruments in the apparatus taught by Kasting, Jr. et al or Holsclaw et al.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.

Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas McGinty can be reached on (571) 272-1029. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregory R. Del Cotto
Primary Examiner
Art Unit 1751

GRD
October 29, 2006